

B/O Form PTO-1390		Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing Under 35 USC 371		Attorney's Docket Number RYAN3004/RE
				09/926599 U.S. Application Number (if known)
International Application Number PCT/GB00/02076	International Filing Date May 30, 2000	Priority Date Claimed May 27, 1999		
Title of Invention AN ANTIMICROBIAL COMPOSITION				
Applicant(s) for DO/EO/US RYAN et al.				

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items under 35 USC 371:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 USC 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 USC 371.
3. ☒ This express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 USC 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
 - ☒ A copy of the International Application as filed 35 USC 371(c)(2).
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
 - ☐ A translation of the International Application into English (35 USC 371(c)(2)).
 - ☒ Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
5. ☐ A translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3)).
6. ☐ An oath or declaration of the inventor(s) (35 USC 371(c)(4)). (☐ Executed ☐ Unexecuted)
7. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)).
8. **Items 11 to 16 below concern other document(s) or information included:**
9. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
10. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
11. ☒ A **FIRST** preliminary amendment.
12. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
13. ☐ A substitute specification.
14. ☐ A change of power of attorney and/or address letter.
15. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and U.S.C. 1.821 - 1.825.
16. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
17. ☐ A second copy of the English translation of the international application under 35 U.S.C. 154(d)(4)
18. ☒ Other items or information: Application Data Sheet

JUL 13 REC'D PLL/PTU 26 NOV 2001

Application Number (if Known) 09/926599		International Application Number PCT/GB00/02076		Attorney's Docket Number RYAN3004/REF	
				Calculations	PTO USE ONLY
1. The following fees are submitted: Basic National Fee (37 CFR 1.492(a)(1)-(5)): <input type="checkbox"/> Neither International Preliminary Examination Fee (37 CFR 1.482) nor International Search Fee (37 CFR 1.445(a)(2)) paid to USPTO \$1040.00 <input checked="" type="checkbox"/> Search report has been prepared by the EPO or JPO \$890.00 <input type="checkbox"/> International Preliminary Examination Fee paid to USPTO (37 CFR 1.482) \$710.00 <input type="checkbox"/> No International Preliminary Examination Fee paid to USPTO (37 CFR 1.482) but International Search Fee paid to USPTO (37 CFR 1.445(a)(2)) \$740.00 <input type="checkbox"/> International Preliminary Examination Fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00					
ENTER APPROPRIATE BASIC FEE AMOUNT				\$ 890.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).					
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	15 -20 =	0	× \$18.00	\$ 0.00	
Independent Claims	1 -3 =	0	× \$84.00	\$ 0.00	
Multiple Dependent Claims (if applicable)			+ \$280.00		
TOTAL OF ABOVE CALCULATIONS				\$ 890.00	
Reduction by ½ for filing by small entity, if applicable. Small Entity Status is asserted pursuant to 37 CFR 1.27 for this application.					
SUBTOTAL				\$ 445.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).					
TOTAL NATIONAL FEE					
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property.					
TOTAL FEES ENCLOSED				\$ 445.00	
			Amount to be:	Refunded:	
				Charged:	

- a. ☒ A check in the amount of **\$445.00** to cover the fees is enclosed.
 b. ☐ Please charge my **Deposit Account Number 02-0200** in the amount of \$_____ to cover the above fees. A duplicate copy of this sheet is enclosed.
 c. ☐ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to **Deposit Account Number 02-0200**. A duplicate copy of this sheet is enclosed.

Note: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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23364
 PATENT TRADEMARK OFFICE

Respectfully submitted,

Richard E. Fichter

Richard E. Fichter

Attorney for Applicant
 Registration Number: 26,382

DATE: November 26, 2001

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

RYAN et al.

U.S. National Phase of PCT/GB00/02076

Entry papers filed herewith November 26, 2001:

For: AN ANTIMICROBIAL COMPOSITION :

Attention: PCT OFFICE

**PRELIMINARY AMENDMENT
AND INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The present application is the U.S. national phase of international application number PCT/GB00/02076.

Please amend the above-identified application as follows:

IN THE SPECIFICATION:

Please add the attached ABSTRACT OF THE DISCLOSURE to the application.

IN THE CLAIMS:

Please replace claims 3-6 and 8 with the following amended claims.

3(Amended). A formulation according to claim 1 comprising by volume, Eucalyptus oil, 4-6% Cajeput oil 0.5-2.5%, Lemongrass oil 1-3%, Clove bud oil 1.5%-3.5%, peppermint oil 0.5-2.5, Piperonyl 1.5-3.5%, Piperonyl Butoxide 0.3-0.9%, Surfactant 0.05-0.15%, 0.5-1.5% lanolin and Water 80-90%.

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4(Amended). A formulation according to claim 1 comprising in approximate amounts by volume, Eucalyptus oil 5.3%, Cajeput oil 1.3, Lemongrass oil 2.0%, Clove bud oil 2.5%, Peppermint oil 1.3%, Piperonyl 2.7%, Piperonyl Butoxide 0.6%, Surfactant (Surfacare T20) 0.1%, lanolin 1% and Water 83.20%.

5(Amended). A formulation according to claim 1 which is further diluted to 1 part formulation to 200 parts water.

6(Amended). A formulation according to claim 1 for use in the treatment of an ectoparasite in an animal.

8(Amended). A formulation according to claim 6 wherein said ectoparasite is blowfly or its larvae.

Please cancel claims 9, 10 and 11 without prejudice or disclaimer and add the following new claims to the application.

13(New) A formulation according to claim 2 comprising by volume, Eucalyptus oil, 4-6% Cajeput oil 0.5-2.5%, Lemongrass oil 1-3%, Clove bud oil 1.5%-3.5%, peppermint oil 0.5-2.5, Piperonyl 1.5-3.5%, Piperonyl Butoxide 0.3-0.9%, Surfactant 0.05-0.15%, 0.5-1.5% lanolin and Water 80-90%.

14(New). A formulation according to claim 2 comprising in approximate amounts by volume, Eucalyptus oil 5.3%, Cajeput oil 1.3, Lemongrass oil 2.0%, Clove bud oil 2.5%, Peppermint oil 1.3%, Piperonyl 2.7%, Piperonyl Butoxide 0.6%, Surfactant (Surfacare T20) 0.1%, lanolin 1% and Water 83.20%.

15(New). A method for treating ectoparasitic infestation of an animal or for repelling said parasites which comprises applying an effective amount of the formulation of claim 1 to the animal.

16(New). A method for treating ectoparasitic infestation of an animal or for repelling said parasites which comprises applying an effective amount of the formulation of claim 2 to the animal.

17(New). A method according to claim 15 wherein the animal is sheep.

18(New). A method according to claim 16 wherein the animal is sheep.

2005/02/26

REMARKS

Applicants have amended the claims in order to reduce the initial filing fee by deleting the multiple dependent claims and by deleting the improper use claims 9, 10 and 11 from the application. The improper use claims have been replaced with method of treatment claims 15 - 18. Applicants retain the right to reintroduce any subject matter canceled by the present Amendment at any time during the prosecution of this application or any further application claiming benefit of this application.

Also, an Abstract of the Disclosure has been added to the application.

Applicants are submitting herewith a copy of the Search Report which issued on International Application No. PCT/GB00/02076, of which the present application is the U.S. national phase. All of the publications cited in the International Search Report are listed on the attached Form PTO-1449. It is Applicants' understanding that, under the procedures of the PCT, copies of the cited publications will have been supplied to the U.S. Patent Office by the International Bureau. However, the Examiner is invited to contact the undersigned attorney if additional copies are necessary or would facilitate examination of the present application.

Otherwise, the Examiner is respectfully requested to return an initialed and dated copy of the attached Form PTO-1449 to confirm that all publications listed thereon have been considered and made officially of record in the file of this application.

Applicants understand that, under the procedures of the PCT, a copy of the priority document (9912443.0, filed May 27, 1999) will have been supplied to the U.S. Patent Office pursuant to Rule 17 of the PCT Regulations. It is therefore respectfully requested that the first Official Action in the present application contain an indication that the appropriate priority document is in the file of this application.

In view of the above amendments, an early action on the application is now in order and is most respectfully requested.

Respectfully submitted,
BACON & THOMAS, PLLC

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PA01.wpd

DATE: November 26, 2001

Marked-Up Version Showing Changes Made

IN THE CLAIMS:

Please replace claims 3-6 and 8 with the following amended claims.

3(Amended). A formulation according to claim 1 [or 2] comprising by volume, Eucalyptus oil, 4-6% Cajeput oil 0.5-2.5%, Lemongrass oil 1-3%, Clove bud oil 1.5%-3.5%, peppermint oil 0.5-2.5, Piperonyl 1.5-3.5%, Piperonyl Butoxide 0.3-0.9%, Surfactant 0.05-0.15%, 0.5-1.5% lanolin and Water 80-90%.

4(Amended). A formulation according to [any preceding claim] claim 1 comprising in approximate amounts by volume, Eucalyptus oil 5.3%, Cajeput oil 1.3, Lemongrass oil 2.0%, Clove bud oil 2.5%, Peppermint oil 1.3%, Piperonyl 2.7%, Piperonyl Butoxide 0.6%, Surfactant (Surfacare T20) 0.1%, lanolin 1% and Water 83.20%.

5(Amended). A formulation according to [any of claims 1 to 4] claim 1 which is further diluted to 1 part formulation to 200 parts water.

6(Amended). A formulation according to [any of claims 1 to 5] claim 1 for use in the treatment of an ectoparasite in an animal.

8(Amended). A formulation according to claim 6 [or 7] wherein said ectoparasite is blowfly or its larvae.

ANTIPARASITIC FORMULATION

The present invention is concerned with an antiparasitic formulation and, in particular, with an antiparasitic formulation which can be used to control ectoparasitic infestation and any contagious diseases resulting therefrom.

Ectoparasitic infections of animals such as sheep are widespread. Such parasites include, for example, ticks, mites, lice, keds, head fly and blow fly, amongst others. Ticks contribute to a condition known as tickborne fever which is an infectious disease affecting almost all sheep which graze tick-infected pastures. It is caused by the microorganism *Cytoecetes phagocytophilia*, a rickettsia transmitted via the bite of sheep ticks. Ticks also contribute to tick pyaemia, or "cripples", which is believed to kill or disable in excess of a quarter of a million lambs each year in the UK. Mites on the other hand cause intense irritation to sheep, which react by rubbing against fence posts, or the like. If no fixed objects are available, they rub against each other spreading the disease further. Mites also cause foot scab, a mange infestation of sheep. Blowfly strike, however, is a particularly nasty condition causing untold misery and death to sheep flocks. It is caused by blowfly which feed on decomposing matter containing liquid protein upon which the blowfly feeds and amongst which it lays its eggs. Any open wound will attract the flies. Once the larvae hatch, the sheep can be literally eaten alive by successive waves of maggots.

Many antiparasitic formulations are known, for example, as pour-on formulations or as total immersion dips for treating sheep. Plunge dipping is a

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technique which is generally used to control certain parasitic infestations of sheep, such as skin parasites, because it allows thorough penetration of the fleece and access to the skin by the antiparasitic formulation. The formulations used to treat ectoparasitic infestations, generally, comprise compounds which contribute to irritancy of or toxicity to the animal upon administration thereto. Examples of such compounds include, diazinon and propetamphos, for example. Other compounds, such as pyrethroids and permethrins are suitable for pour-on formulations, whilst in plunge dips it is the organophosphates which are frequently used.

These compounds are toxic not only to the animals but to the administrators alike. Furthermore, many sheep dip formulations cannot be used to treat, for example, larval infestation of wounds such as in the case of the larvae of blowfly which feed on the dead and damaged tissue associated with wounds or scouring. Treatment of blowfly larvae is normally carried out using mild insecticidal creams. Toxic substances, such as contained in many sheep dips, cannot be applied because under no circumstances can the above mentioned formulations be applied to open wounds. The formulations used previously also contribute to serious environmental and ecological damage if they are released into the environment. The use of these compounds must therefore be tightly controlled and a considerable number of regulations apply to, for example, disposal of sheep dips.

Accordingly, there exists a need for formulations which when applied to an animal can effectively eradicate common ectoparasitic infestation and any resulting contagious diseases and which formulation similarly alleviates or ameliorates the disadvantages

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described above whilst minimising trauma and shock to the animal.

Therefore, there is provided by a first aspect of the present invention, an antiparasitic formulation comprising in an antiparasitically effective amount, Eucalyptus oil, Cajeput oil, Lemongrass oil, Clove bud oil, Peppermint oil, Piperonyl and Piperonyl Butoxide. Preferably, the formulation is further diluted with water and in such an embodiment an amount of a suitable surfactant is also included in the formulation in addition to lanolin.

In a preferred embodiment, the formulation comprises:

	% By Volume
Eucalyptus oil	4-6
Cajeput oil	0.5-2.5
Lemongrass oil	1-3
Clove bud oil	1.5-3.5
Peppermint oil	0.5-2.5
Piperonyl	1.5-3.5
Piperonyl Butoxide	0.3-0.9
Surfactant	0.05-0.15
Lanolin	0.5-1.5
Water	80-90%

Preferably, however, the formulation comprises in approximate amounts by volume, 5.3% Eucalyptus oil, 1.3% Cajeput oil, 2.0% Lemongrass oil, 2.5% Clove bud oil, 1.3% Peppermint oil, 2.7% Piperonyl, 0.6% Piperonyl Butoxide, Surfactant 0.1%, lanolin 1% and water 83.20%.

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In a preferred embodiment the formulation may be further diluted to 1 part formulation per 200 parts water, for use as a sheep dip.

5 The formulations according to the invention are particularly advantageous because they avoid the use of hazardous compounds such as organophosphates which can be toxic both to the animal the uses and the environment. The absence of such compounds also
10 minimises any trauma, shock or irritancy to the animal. The formulations are also safe for use by humans without risk to health and they are also considerably less damaging to the environment. The oils used are registered with the Department of Novel
15 Foods and Flavours at the Ministry of Agriculture Fisheries and Foods. Neither the Council of Europe's Committee of Experts on Flavouring Substances nor any other European committee has recommended limits on the use of these essential oils. These oils have been
20 evaluated by the US Flavouring Extract Manufacturers' Association (FEMA) who have classified them as GRAS (Generally Recognised As Safe) in 1965. These assessments were published in a paper Hall R.L. and Oser B.L. (1965). The formulations of the present
25 invention therefore avoid the use of any organophosphates, permethrins, pyrethrums or derivatives thereof so they are significantly safer for the animal, the operator and the environment.

30 In another aspect of the invention, the formulation according to the invention may, advantageously, be used in the treatment of an animal body so as to, for example, treat ectoparasitic infestation, such as, in sheep, and also any subsequent contagious diseases
35 resulting from the infestation.

According to a further aspect of the invention, there

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is also provided use of a formulation according to the invention for the manufacture of a medicament for treating an animal of ectoparasitic infestation. The formulations may be applied directly to the animal but preferably are used in a total immersion dip, such as used in a sheep dip, thus allowing the formulation to sufficiently penetrate the fleece so as to substantially eradicate the infestation.

External parasites of sheep include, amongst others, *Damalinia ovis* (biting louse), *Linognathus ovillus* (sucking louse), *Lucilia spp* (blowfly), *Culicoides* (midges), *Hydrotaea irritans* (headfly). The formulation of the invention may be used to control infestation of sheep by these parasites. Other parasites that may be effectively eradicated by the formulation of the invention include scab mite (*Psoroptes Communia Ovis*), tick pyremia and other tick borne fever, sarcoptic mange and keds. The formulation of the invention is, however, particularly useful in repelling the blowfly parasite and in eradicating the larvae of the blowfly which infest open wounds in sheep or areas where scouring occurs. Thus, the formulation is particularly advantageous by virtue of its use as a dip formulation and yet which is sufficiently non-toxic to the animal that it can also be used, not only to repel the blowfly but to eradicate blowfly larvae, which cannot normally be treated with sheep dip formulations.

As is known, oil of eucalyptus is obtained from various species of eucalyptus and the resulting oils do not possess a uniform analysis. It is believed, however, that the properties of the eucalyptus oil according to the invention are not dependent on a particular source of oil of eucalyptus and one may use oil derived from *Eucalyptus globulus* and/or *Eucalyptus*

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dives. Eucalyptus oil is rich in cineole and desirably eucalyptus oil according to the invention comprises cineole and preferably 1-8 cineole in an amount of from approximately 35 to 90% by volume.

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The invention may be more clearly described by reference to the following example:

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A formulation according to the invention was prepared by combining and mixing all of the oils of the following ingredients in the approximate amounts provided:

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	% product
Eucalyptus oil	5.3
Cajeput oil	1.3
Lemongrass oil	2.0
Clove bud oil	2.5
Peppermint oil	1.3
Piperonyl	2.7
Piperonyl Butoxide	0.6
Surfacare T20	0.1
Lanolin	1%
Water	83.20
Total	100%

30

The essential oils together with piperonyl and piperonyl butoxide are mixed. The mixture is then slowly stirred at ambient temperature and then the surfactant is added in addition to a small amount of water and lanolin. The mixture is then high shear stirred to a cream consistency before the final addition of water up to the percentage amount identified above. The product is then pH tested and

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sampld against a GC standard. Application of the formulation to sheep by way of a plunge dip served to alleviate infestation of sheep by their common parasites.

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EXAMPLE

A number of field trials were conducted to evaluate the effectiveness of the above composition in treating ectoparasitic infection of sheep. A solution of the composition further diluted to 1 part composition to 200 parts water was prepared for application by way of a plunge dip. The dipping tank held approximately 400 gallons. 1000 animals were passed through the dipping tank. Each animal absorbed approximately 1.5 litres of solution in the fleece. After each 75 lamb/ewe dip the dipping tank was further topped up with the same solution to make up 400 gallons. After this field trial on 2 July 1999, all animals were protected from blowfly and other ectoparasitic infestations until September when a further dip was performed. The period between July and September is the most crucial as at least 70 out of every 1000 animals suffer blowfly strike during this period.

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In further tests, the formulation of the invention was applied directly to healthy live specimens of ticks, blowfly and their maggots, headfly, the mite psoroptes communia ovis that causes sheep scab, redmite, and both types of lice. The formula of the invention induced 100% death of all these parasites in less than one minute.

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CLAIMS

1. An antiparasitic formulation comprising
Eucalyptus oil, Cajeput oil, Lemongrass oil, Clove bud
oil, Peppermint oil, Piperonyl and Piperonyl Butoxide.

2. A formulation according to claim 1, further
diluted with water and comprising an appropriate
surfactant and lanolin.

3. A formulation according to claim 1 or 2
comprising by volume, Eucalyptus oil, 4-6% Cajeput oil
0.5-2.5%, Lemongrass oil 1-3%, Clove bud oil 1.5%-
3.5%, peppermint oil 0.5-2.5, Piperonyl 1.5-3.5%,
Piperonyl Butoxide 0.3-0.9%, Surfactant 0.05-0.15%,
0.5-1.5% lanolin and Water 80-90%.

4. A formulation according to any preceding claim
comprising in approximate amounts by volume,
Eucalyptus oil 5.3%, Cajeput oil 1.3, Lemongrass oil
2.0%, Clove bud oil 2.5%, Peppermint oil 1.3%,
Piperonyl 2.7%, Piperonyl Butoxide 0.6%, Surfactant
(Surfacare T20) 0.1%, lanolin 1% and Water 83.20%.

5. A formulation according to any of claims 1 to 4
which is further diluted to 1 part formulation to 200
parts water.

6. A formulation according to any of claims 1 to 5
for use in the treatment of an animal.

7. A formulation according to claim 6 wherein said
animal is a sheep.

8. A formulation according to claim 6 or 7 wherein
said ectoparasite is blowfly or its larvae.

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9. Use of a formulation according to any of claims 1 to 5 in the manufacture of a medicament for treating ectoparasitic infestation of an animal or for repelling said parasites.

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10. Use according to claim 9 wherein said animal is a sheep.

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11. Use according to claim 9 or 10 wherein said ectoparasite is blowfly or its larvae.

12. A sheep dip comprising a formulation according to claim 5.

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CONTINUATION OF DECLARATION FOR PATENT APPLICATION AND APPOINTMENT OF ATTORNEY

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DATE <u>11-3-2002</u>	SIGNATURE <u>S. Morris</u>

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DATE	SIGNATURE

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☐ See following pages for additional joint inventors/priority applications.

(04AUG1)